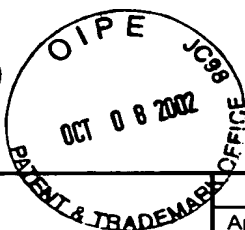


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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/443,683
Filing Date	November 19, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

Sheet 1 of 4

### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	1	2803582		Cherney	8/20/1957	
	2	3137631		Soloway et al.	6/16/1964	
	3	3216897		Krantz	11/9/1965	
	4	3274063		Nieper et al.	9/20/1966	
	5	3594476		Merrill	7/20/1971	
	6	3715432		Merrill	2/6/1973	
	7	3755557		Jacobs	8/28/1973	
	8	3794476		Michalik et al.	2/26/1974	
	9	3937668		Zolle	2/10/1976	
	10	3960757		Morishita et al.	6/1/1976	
	11	3965255		Bloch et al.	6/22/1976	
	12	4016100		Suzuki et al.	4/5/1977	
	13	4053585		Allison et al.	10/11/1977	
	14	4056635		Glen et al.	11/1/1977	
	15	4073943		Wretlind et al.	2/14/1978	
	16	4078052		Papahadjopoulos	3/7/1978	
	17	4089801		Schneider	5/16/1978	
	18	4102806		Kondo et al.	7/25/1978	
	19	4107288		Oppenheim et al.	8/15/1978	
	20	4133874		Miller et al.	1/9/1979	
	21	4145410		Sears	3/20/1979	
	22	4147767		Yapel, Jr.	4/3/1979	
	23	4186183		Steck et al.	1/29/1980	
	24	4219548		Reller	8/26/1980	
	25	4235871		Papahadjopoulos et al.	11/25/1980	
	26	4241046		Papahadjopoulos et al.	12/23/1980	
	27	4271196		Schmidt	6/2/1981	
	28	4280996		Okamoto et al.	7/28/1981	
	29	4298594		Sears et al.	11/3/1981	
	30	4302459		Steck et al.	11/24/1981	
	31	4308166		Marchetti et al.	12/29/1981	
	32	4309421		Ghyczy et al.	1/5/1982	
	33	4316884		Alam et al.	2/23/1982	
	34	4320121		Sears	3/16/1982	
	35	4325871		Sasaki et al.	4/20/1982	
	36	4328222		Schmidt	5/4/1982	
	37	4329332		Couvreux et al.	5/11/1982	

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*[Signature]*

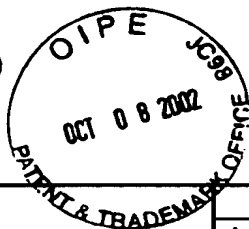
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/443,683
Filing Date	November 19, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

Sheet 2 of 4

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		Application or Patent Number	Kind Code			
b	38	4331654		Morris	5/25/1982	
	39	4332795		Ghyczy et al.	6/1/1982	
	40	4332796		Los	6/1/1982	
	41	4340594		Mizushima et al.	7/20/1982	
	42	4345588		Widder et al.	8/24/1982	
	43	4378354		Ghyczy et al.	3/29/1983	
	44	4394372		Taylor	7/19/1983	
	45	4397846		Weiner et al.	8/9/1983	
	46	4411894		Schrank et al.	10/25/1983	
	47	4421747		Ghyczy et al.	12/20/1983	
	48	4427649		Dingle et al.	1/24/1984	
	49	4448765		Ash et al.	5/15/1984	
	50	4483847		Augart	11/20/1984	
	51	4485054		Mezei et al.	11/27/1984	
	52	4492720		Mosier	1/8/1985	
	53	4515736		Deamer	5/7/1985	
	54	4529561		Hunt et al.	7/16/1985	
	55	4532089		MacDonald	7/30/1985	
	56	4610868		Fountain et al.	9/9/1986	
	57	4613505		Mizushima et al.	9/23/1986	
	58	4622219		Haynes	11/11/1986	
u	59	4675236		Ohkawara et al.	6/23/1987	
	60	4687762		Fukushima et al.	8/18/1987	
	61	4725442		Haynes	2/16/1988	
	62	4756910		Yagi et al.	7/12/1988	
	63	4758598		Gregory	7/19/1988	
	64	4761288		Mezei	8/2/1988	
	65	4762720		Jizomoto	8/9/1988	
	66	4766046		Abra et al.	8/23/1988	
	67	4776991		Farmer et al.	10/11/1988	
	68	4801455		List et al.	1/31/1989	
	69	4803070		Cantrell et al.	2/7/1989	
	70	4806350		Gerber	2/21/1989	
	71	4806352		Cantrell	2/21/1989	
	72	4826687		Nerome et al.	5/2/1989	
	73	4839111		Huang	6/13/1989	

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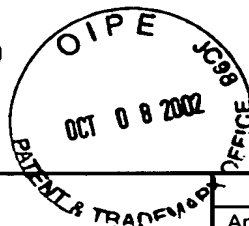
*Kishore*

Date Considered

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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**Complete if Known**

Application Number	09/443,683
Filing Date	November 19, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYEPHARMA

Sheet	3	of	4
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## U.S. PATENT DOCUMENTS

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/443,683
Filing Date	November 19, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

Sheet 4 of 4

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
km	88	DE	2 513 797		Imperial Chemical Industries (See Doc. No. 14)	10/9/1975		+
	89	DE	2 938 807		Green Cross Corp. (See Doc. No. 28)	11/13/1980		+
	90	EP	0 052 322		Gersonde, Klaus	5/26/1982		+
	91	EP	0 272 091		Vestar, Inc.	6/22/1988		
	92	EP	0 418 153		Medgenix Group, S.A. (See Doc. No. 78)	3/20/1991		+
	93	EP	0 456 670		B. Braun Melsungen AG	11/21/1991		+
	94	EP	0 456 764		B. Braun Melsungen AG	11/21/1991		+
	95	EP	0 499 299		Sterling Winthrop Inc.	8/19/1992		
	96	EP	0 193 208		Technicon Instruments Corp.	11/6/1991		
	97	GB	2,046,094		A. Nattermann & Cie	11/12/1980		
	98	JP	1-502590		Liposome Technology, Inc. (See Doc. No.106)	7/9/1989		
	99	JP	55141407		A. Nattermann & Cie (See Doc. No. 32)	11/5/1980		+
	100	JP	60208910		Green Cross Corp.	10/21/1985		+
	101	JP	63233915		Besutas Res Inc (See Doc. No. 84)	9/29/1988		+
	102	JP	63502117		Liposome Technology, Inc. (See Doc. No.105)	8/13/1987		+
	103	PCT	WO 0030616		RTP Pharma Inc	6/2/2000		
	104	PCT	WO 8500011		University of Miami	1/3/1985		
	105	PCT	WO 8704592		Liposome Technology, Inc.	8/13/1987		
	106	PCT	WO 88/04924		Liposome Technology, Inc.	7/14/1988		
	107	PCT	WO 9104011		Riker Laboratories, Inc.	4/4/1991		

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

Complete if Known

Application Number	09/443,863
Filing Date	November 19, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
[Handwritten Initials]	1	4340594		Mizushima et al.	7/20/1982	
	2	4351831		Growdon et al.	9/28/1982	
	3	4356167		Kelly	10/26/1982	
	4	4369182		Ghyczy et al.	1/18/1983	
	5	4371516		Gregory et al.	2/1/1983	
	6	4411933		Samejima et al.	10/25/1983	
	7	4629626		Miyata et al.	12/16/1986	
	8	4800079		Boyer	1/24/1989	
	9	4880634		Speiser	11/14/1989	
	10	4895726		Curtet et al.	1/23/1990	
	11	4961890		Boyer	10/9/1990	
	12	4963367		Ecanow	10/16/1990	
	13	4990337		Kurihara et al.	2/5/1991	
	14	5169847		Nagy nee Kricsfalussy et al.	12/8/1992	
	15	5179079		Hansen et al.	1/12/1993	
	16	5217707		Szabo et al.	6/8/1993	
	17	5298262		Na et al.	3/29/1994	
	18	5304564		Tsuboi et al.	4/19/1994	
	19	5326552		Na et al.	7/5/1994	
	20	5336507		Na et al.	8/9/1994	
	21	5340564		Illig et al.	8/23/1994	
	22	5346702		Na et al.	9/13/1994	
	23	5352459		Hollister et al.	10/4/1994	
	24	5360593		Bapatia	11/1/1994	
	25	5364633		Hill et al.	11/15/1994	
	26	5389377		Chagnon et al.	2/14/1995	
	27	5399363		Liversidge et al.	3/21/1995	
	28	5447710		Na et al.	9/5/1995	
	29	5470583		Na et al.	11/28/1995	
	30	5510118		Bosch et al.	4/23/1996	
	31	5527537		Dietl	6/18/1996	
	32	5545628		Deboeck et al.	8/13/1996	
	33	5552160		Liversidge et al.	9/3/1996	
	34	5560931		Eickhoff et al.	10/1/1996	
	35	5569448		Wong et al.	10/29/1996	
	36	5571536		Eickhoff et al.	11/5/1996	
	37	5576016		Amselem et al.	11/19/1996	
	38	5578325		Domb et al.	11/26/1996	

Examiner Signature <span style="float: right;">[Handwritten Signature]</span>	Date Considered <span style="float: right;">3/03</span>
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	2	of	5
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Application Number	09/443,863
Filing Date	November 19, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYEPhARMA

## U.S. PATENT DOCUMENTS

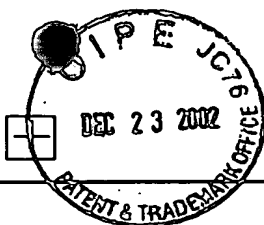
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
64	39	5589455		Woo	12/31/1996	
	40	5603951		Woo	2/18/1997	
	41	5639474		Woo	6/17/1997	
	42	5645856		Lacy et al.	7/8/1997	
	43	5656289		Cho et al.	8/12/1997	
	44	5660854		Haynes et al.	8/26/1997	
	45	5660858		Parikh et al.	8/26/1997	
	46	5662932		Amselem et al.	9/2/1997	
	47	5663198		Reul et al.	9/2/1997	
	48	5676928		Klaveness et al.	10/14/1997	
	49	5776495		Duclos et al.	7/7/1998	
	50	5827536		Laruelle	10/27/1998	
	51	5827822		Floc'h et al.	10/27/1998	
	52	5834025		de Garavilla et al.	11/10/1998	
	53	5851275		Amidon et al.	12/22/1998	
	54	5858398		Cho	1/12/1999	
	55	5858410		Muller et al.	1/12/1999	
	56	5880148		Edgar et al.	3/9/1999	
	57	5932243		Fricker et al.	8/3/1999	
	58	5972366		Haynes et al.	10/26/1999	
64	59	6045829		Liversidge et al.	4/4/2000	
	60	6046163		Stuchlik et al.	4/4/2000	
	61	6057289		Mulye	5/2/2000	
	62	6063762		Hong et al.	5/16/2000	
	63	6086376		Moussa et al.	7/11/2000	
	64	6096338		Lacy et al.	8/1/2000	
	65	6228399		Parikh et al.	8/8/2001	
	66	6267989		Liversidge et al.	7/31/2001	
	67	6270806		Liversidge et al.	8/7/2001	
	68	6337092		Khan et al.	1/8/2002	
64	69	6387409		Khan et al.	5/14/2002	
	70	RE32393		Wretlind et al.	4/7/1987	

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Application Number	09/443,863
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Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

Sheet 3 of 5

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>+</sup>
G	71	DE	3 421 468		R. Arzneimittel GmbH & Co. (see Doc. No. 9)	12/19/85		X <sup>+</sup>
	72	DE	4 440 337		DDS Drug Delivery Serv. (see Doc. No. 55)	5/15/96		X <sup>+</sup>
	73	EP	0 330 532		Fournier Industrie ET SANTE (see Doc. No. 10)	12/16/92		X <sup>+</sup>
	74	EP	0 391 369		Yissum Research Dev. Co. of the Hebrew Univ. of Jerusalem	10/10/90		
	75	EP	0 570 829		Dietl (see Doc. No. 31)	11/24/93		X <sup>+</sup>
	76	EP	0 580 690		Sandoz Ltd.	2/2/94		
	77	EP	0 601 618		Sterling Winthrop Inc.	6/15/94		
	78	EP	0 602 700		Sterling Winthrop Inc.	6/22/94		
	79	EP	0 724 877		Fournier Labs S.C.A. (see Doc. No. 56)	8/7/96		X <sup>+</sup>
	80	EP	0 757 911		CL Pharma (see Doc. No. 50)	2/12/97		X <sup>+</sup>
	81	EP	0 605 497		Medac Gesellschaft Für Klinische Spezialpräparate GmbH (see Doc. No. 92)	7/13/94		X <sup>+</sup>
	82	FR	2 617 047		Sanofi, S.A. & Fournier Labs.	12/30/88		X <sup>+</sup>
	83	GB	1 527 638		Bauer et al.	10/4/78		
	84	HU	211 580		Sándorné et al. (see Doc. No. 14)	6/20/95		X <sup>+</sup>
	85	JP	56167616		Green Cross Corp. (see Doc. No. 1)	5/15/80		X <sup>+</sup>
	86	PCT	WO 00/10531		RTP Pharma Inc.	3/2/00		
	87	PCT	WO 00/30615		RTP Pharma Inc.	6/2/00		
	88	PCT	WO 00/40219		Dexcel, Ltd.	7/13/00		
	89	PCT	WO 00/41682		LG Chemical Ltd.	7/20/00		
	90	PCT	WO 01/30372		BASF Aktiengesellschaft	5/3/01		
	91	PCT	WO 92/18105		Sandoz Ltd.	10/29/92		
	92	PCT	WO 93/05768		Medac Gesellschaft Für Klinische Spezialpräparate GmbH	4/1/93		
	93	PCT	WO 94/20072		Pharmacia AB	9/15/94		
	94	PCT	WO 96/21439		Galephar P.R. Inc.	7/18/96		
	95	PCT	WO 96/24332		Nanosystems L.L.C.	8/15/96		
	96	PCT	WO 97/14407		Research Triangle Pharmaceuticals	4/24/97		
	97	PCT	WO 98/41239		Nycomed Imaging AS	9/24/98		
	98	PCT	WO 99/29300		RTP Pharma Inc.	6/17/99		
	99	PCT	WO 99/29316		Cyclosporine Therapeutics Ltd.	6/17/99		
	100	PCT	WO 99/49846		RTP Pharma Inc.	10/7/99		
	101	PCT	WO 99/49848		RTP Pharma Inc.	10/7/99		

Examiner Signature

Kishore

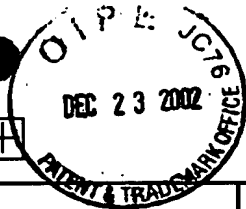
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 4 of 5

Complete if Known

Application Number	09/443,863
Filing Date	November 19, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	G. Kishore
Attorney Docket Number	401930/SKYE PHARMA

## **OTHER - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
W	1 0 2	ROSS et al., "Aqueous Solutions of Surface-Active Solutes", <i>Colloidal Systems and Interfaces</i> , © 1988, pp. 148-151		
	1 0 3	SANDE et al., "Antimicrobial Agents: Antifungal and Antiviral Agents", pp. 1219-1222		
	1 0 4	BITTMAN, ROBERT, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," <i>Lipids</i> , 1978, Vol. 13, No. 10, pp. 686-691		
	1 0 5	MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, June 2000, pp. 21-30		
	1 0 6	BANGHAM et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <i>J. Mol. Biol.</i> , 1965, Vol. 3, pp. 238-252		
	1 0 7	HUANG et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature", <i>Biochem. Journal</i> , 1999, Vol. 8, pp. 593-603		
	1 0 8	GREGORIADIS, GREGORY, "The Carrier Potential of Liposomes in Biology and Medicine", <i>New Engl. J. Med.</i> , 1976, Vol. 295, No. 13, pp. 704-710		
	1 0 9	CUDD et al., "Liposomes Injected Intravenously into Mice Associate with Liver Mitochondria", <i>Biochem. Biophys. Acta.</i> , 1984, Vol. 774, pp. 169-180		
	1 1 0	BENZ et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers Made from Monolayers", <i>Biochem. Biophys. Acta</i> , 1975, Vol. 394, pp. 323-334		
	1 1 1	GOODMAN and GILLMAN'S, "The Pharmacological Basis of Therapeutics," 7 <sup>th</sup> Ed., <i>MacMillan Publishing Co.</i> , New York (1985), Chap. 15, p. 312		
	1 1 2	CHERNEY, L.S., "Tetracaine Hydroiodide: A Long Lasting Local Anesthetic Agent for the Relief of Postoperative Pain", <i>Anesth. Analg.</i> , 1963, Vol. 42, No. 4, pp. 477-481		
	1 1 3	HAYNES et al., "Metal-Ligand Interactions in Organic Chemistry and Biochemistry", B. Pullman and N. Goldblum (Eds.), part 2, 1977, pp. 189-212		
	1 1 4	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets", <i>Anesthesiology</i> , 1985, Vol. 63, No. 5, pp. 490-499		
	1 1 5	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Intra-Dermal Injection of Lecithin-Coated Methoxyflurane Microdroplets", <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 1987, Vol. 14, pp. 293-294		
	1 1 6	KIRKPATRICK et al., "Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man," <i>Anesthesiology</i> , 1987, Vol. 67(3A) p. A254		
	1 1 7	GENNARO et al., (Eds.), "Sustained-Release Drug Therapy," <i>Remington's Pharmaceutical Sciences</i> , 1985, 17 <sup>th</sup> Ed., p. 1645		
	1 1 8	"Derived Diameters and Distribution Statistics," from an unknown web-site, 6 pages		
	1 1 9	"Getting Started", Man 0106, Issue 1.0, <i>Malvern Instruments Ltd.</i> , England (Jan. 1996), pp. 7.1-7.7		

Examiner Signature

*Khe*

Date Considered

3/03

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 5

Complete if Known

Application Number 09/443,863  
Filing Date November 19, 1999  
First Named Inventor PARIKH  
Group Art Unit 1615  
Examiner Name G. Kishore  
Attorney Docket Number 401930/SKYE PHARMA

### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
L	120	CHULIA et al., (Eds.) "Powder Technology and Pharmaceutical Processes", Amsterdam (1994), pp. 66-67.		
	121	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms, Tablets</i> , 1980, Vol. 1, p. 13		
	122	MIYAJIMA, KOICHIRO, "Role of Saccharides for the Freeze-Thawing and Freeze-Drying of Liposome", <i>Advanced Drug Delivery Review</i> , 1997, Vol. 24, pp.151-159		
	123	BUCHMULLER et al., "Cryopel: Ein neues Verfahren zum Pelletieren und Frosten Biologischer Substrate," <i>Gas Aktuell</i> , 1989, Vol. 35, pp. 10-13		X
	124	WU et al., "Pharmacokinetics of Methoxyflurane After Its Intra-Dermal Injection as Lecithin-Coated Microdroplets," <i>Journal of Controlled Release</i> , 1989, Vol. 9, pp. 1-12		
	125	PACE et al., "Novel Injectable Formulations of Insoluble Drugs", <i>Pharmaceutical Technology</i> , March 1999, Vol. 23, No. 3, pp. 116-134		
	126	ROMPP'S CHEMIE LEXIKON, (Dr. Hermann Rompp), "Emulsion", 2 Aufl., Bd. 1, Stuttgart (1950)		X
	127	BERGMANN, LUDWIG, <i>Der Ultraschall</i> , 5 Aufl., 1949, Stuttgart, S. 551-564, 672f		X
	128	LEHNINGER, ALBERT L., "The Molecular Basis of Cell Structure and Function", <i>Biochemistry</i> , 1970, Chapter 10		
	129	GUZMAN et al., "Formation and Characterization of Cyclosporine-Loaded Nanoparticles", <i>1088 J. Pharm. Sci.</i> 1993, Vol. 82, No. 5, pp. 498-502		
	130	NAPPER, DONALD H., "Polymeric Stabilizations of Colloidal Dispersions", 1983.		
	131	MULLER et al., <i>Emulsions and Nanosuspensions</i> , 1998, Chapter 9, p. 163		
	132	LOURENCO et al., "Steric Stabilization of Nanoparticles: Size and Surface Properties", <i>Int. J. of Pharm.</i> , 1996, Vol. 138, pp. 1-12		
J	133	LUCKHAM, PAUL F., "The Physical Stability of Suspension Concentrates with Particular etc.", <i>Pestic. Sci.</i> , 1989, Vol. 25, pp.25-34		
	134	CALVOR et al., "Production of Microparticles by High-Pressure Homogenization", <i>Pharm. Dev. Tech.</i> , 1998, Vol. 3(3), pp. 297-205		
	135	LAFUMA, FRANCOISE, "The Role of Water-soluble Polymers at the Solid/Liquid Interface in the Mechanisms of Flocculation/Stabilization of Aqueous Colloidal Suspensions", <i>[LSP4]La Fuma Polymery</i> , 1998, Vol. 43, nr 2, pp. 104-108,		
	136	Website <a href="http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm">http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm</a>		
	137	SIEKMANN et al., "Melt-homogenized Solid Lipid Nanoparticles Stabilized by the Non-ionic Surfactant Tyloxapol", <i>Pharm. Pharmacol Lett.</i> , 1994, Vol. 3, pp.225-228		
	138	MULLER et al., "Nanosuspensions for the I.V. Administration of Poorly Soluble Drugs-Stability During Sterilization and Long-Term Storage", <i>Dept. of Pharmaceutics, Biopharmaceutics and Biotechnology</i> , The Free University of Berlin, Kelchstraße 31, D-12169 Berlin, Germany		
	139	ZUIDAM et al., "Sterilization of Liposomes by Heat Treatment", <i>Pharmaceutical Research</i> , 1993, Vol. 10, No. 11, pp. 1591-1596		

Examiner Signature	<i>Kishore</i>	Date Considered	3/03
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